## REMARKS

### Status of the Claims

With this amendment, claims 1-10 are pending.

Claims 1-5, 7, and 9 have been amended to more particularly point out and distinctly claim the subject matter being prosecuted in this application. Amended claim 1 recites an isolated nucleic acid molecule encoding a *B.anthracis* LuxS polypeptide sequence that is a least 90% identical to the amino acid sequence set forth in SEQ ID NO: 2. Support for amended claim 1 may be found, for example, on page 4, lines 18-20 of the specification as filed.

Amended claim 2 recites that the *B.anthracis* LuxS polypeptide that is encoded by the isolated nucleic acid molecule of claim 1 is capable of catalyzing the formation of AI-2. Support for amended claim 2 may be found, for example, on page 2, lines 28-29 to page 3, lines 1-2 of the specification as filed.

Claim 3, as been amended, depends from claim 1 rather than claim 2. Support for amended claim 3 may be found, for example, on page 4, lines 20-22 of the specification as filed.

Claims 4 and 7 have been amended to improve their forms so that each claim recites as an independent claim. Claim 5 has been amended to read as an independent claim. Specifically, amended claim 5 recites an isolated nucleic molecule encoding a *B. anthracis* LuxS polypeptide, wherein the nucleotide sequence is at least 80 % identical to the nucleotide sequence set forth in SEQ ID NO: 1, and wherein the polypeptide is capable of catalyzing the formation of AI-2. Support for amended claim 5 may be found, for example, on page 4, lines 22-24 of the specification as filed.

Claim 9 has been amended to recite an isolated host cell, as suggested by the Examiner in the paragraph bridging pages 3-4 of the March 20, 2007 Office Action. Support for

amended claim 9 may be found, for example, on page 15, line 10 to page 21, lines 17 of the specification as filed.

None of the claim amendments adds new matter. Entry of the amendments and reconsideration of the pending claims is respectfully requested.

**Specification - Informalities**

Sequence Listing

The Examiner has objected to the amino acid sequences in Figure 4 for containing sequences over four amino acids without identification by specific SEQ ID NOs as required by 37 C.F.R. § 1.821-1.825.

Figure 4 has been amended to insert sequence identifiers as required by 37 C.F.R. § 1.821-1.825.

Use of Trademarks

The Examiner has noted the use of trademarks in the specification and requires that each trademark recitation be capitalized.

The specification has been amended to insert proper trademark symbols and the accompanying generic terminology to respect the proprietary nature of the marks.

Embedded Hyperlink

The Examiner has objected to the embedded hyperlink on page 30, line 12 and the first paragraph of the Example 1.

The term "http://" has been removed from the Uniform Resource Locators (URLs) referenced above. As required by MPEP 608.01, the URLs are no longer interpreted as valid HTML code, and therefore are not live world wide web links.

**Claim Rejection - 35 U.S.C. § 101**

Claim 9[1] has been rejected as allegedly being directed to non-statutory subject matter.

Claim 9 has been amended to recite "an isolated host cell" as suggested by the Examiner. Support for this amendment may be found at least on page 15, line 10 to page 21, lines 17 of the specification as filed. It is respectfully submitted that the rejections under 35 U.S.C. § 101 have been fully obviated and should be withdrawn.

**Claim Rejection - 35 U.S.C. § 112, First Paragraph ("Written Description")**

Claims 1-5 and 7 have been rejected as allegedly failing to comply with the written description requirement. The Examiner asserts that the claims encompass a genus of nucleic acid molecules and polypeptides without specifying a function, or teaching the structure or relevant identifying characteristics of a representative number of species within the claimed polypeptide genus or nucleic acid molecule genus. The Examiner also asserts that although the specification discloses the sequences of SEQ ID NOs: 1 and 2, it does not disclose any specific variant sequences. The rejection is respectfully traversed.

The Examiner mistakenly focuses only on one aspect of the requirement for written description. Claims to a genus are described either by recitation of a representative number of

[1] Applicants believe that the Examiner inadvertently referred to claim 8 instead of claim 9 (See Office Action on page 3, paragraph 8.).

species, or by the disclosure of shared structural features of the genus. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997). In other words, it is not required that a specific variant sequence be disclosed.

Here, the amended claims of the instant application disclose two shared structural features: 1) isolated nucleic acid molecules encoding a polypeptide that is at least 90% identical to the amino acid sequence set forth in SEQ ID NO: 2 and 2) nucleic acid molecules encoding a *B.* anthracis Lux S polypeptide. The specification states the art-recognized correlation between the structure of the invention and its function. Specifically, the specification defines "Lux S polypeptide" to mean a polypeptide capable of converting *S*-ribosylhomocysteine to 4,5-dihydroxyl-2,3-pentanedione (DPD) ( *See,* page 14, lines 13-14), which catalyzes AI-2 formation (*See*, page 2, lines 28-29 to page 3, lines 1-2). A person of ordinary skill having read the specification would understand that the present claims call for 1) nucleic acid molecules sharing a common structural feature (i.e., encoding for an amino acid having 90% sequence identity with the sequence set forth in SEQ ID NO: 2). Additionally, the person of ordinary skill would also understand that the claims require the nucleic acid molecules to encode a Lux S polypeptide which is defined by the specification as converting *S*-ribosylhomocysteine to 4,5-dihydroxyl-2,3-pentanedione (DPD), which catalyzes the formation of AI-2. Thus, the written description requirement is fulfilled by the disclosure that the claims require 90% identity to the SEQ ID NO: 2 and specify that the isolated nucleic acid molecules encode a *B.* anthracis Lux S polypeptide.

The test for compliance with the written description requirement is that the specification must contain sufficient information to persuade a person of ordinary skill that the inventor was in possession of the invention defined by the claims. *Vas-Cath, Inc. v. Mahurkar,* 935 F.2d 1555, 1563 (Fed. Cir. 1991). As discussed above, the present specification as filed satisfies this test. Based upon a reading of the specification, a person of ordinary skill in the art would have concluded that the present inventors were in possession of the isolated nucleic acid molecules and

polypeptides that are called for by the present claims. The specification on page 11, lines 3-9 discloses a definition of substantially identical which encompasses a polypeptide or nucleic acid molecule that has 80% identity or 90% identity to a reference amino acid or nucleic acid sequence such as SEQ ID NO: 2 or SEQ ID NO:1, respectively. The specification on page 11, lines 10-16, for example, also teaches how to determine sequence identity between any two nucleic acid molecules or two polypeptides using sequence comparison and alignment algorithms that are well-known to those skilled in the art such as BLAST, FASTA, DNA Strider, and GCG package. The use of such sequence comparison and alignment alogrightms is routine and well within the knowledge of a worker skilled in the art at the time the present invention was made. Additionally, a person of skill in the art could readily envision all the DNAs degenerate to SEQ ID NO: 1 by using a genetic code table. All the details of the present claims are fully described in sufficient detail to persuade those skilled in the art that the present inventors were in possession of the claimed invention.

Based upon the teachings in the specification, one of skill in the art would appreciate that at the time of filing the present application the inventors were in possession of isolated nucleic acid molecules encoding a *B.* anthracis Lux S polypeptide that is at least 90% identical to the amino acid sequence set forth in SEQ ID NO: 2 and for an isolated nucleic acid molecule encoding a *B.* anthracis Lux S polypeptide comprising a nucleotide sequence that is at least 80% identical to the nucleotide sequence of SEQ ID NO: 1. The information set forth in the specification establishes that the inventors had possession of the isolated nucleic acid molecules and polypeptides called for by the present claims at the time this application was filed.

For all the foregoing reasons, it is submitted that the rejections under 35 U.S.C. § 112, paragraph 1, have been overcome and should be withdrawn.

**Claim Rejection - 35 U.S.C. § 112, First Paragraph ("Enablement")**

Claims 1, 2, 3, 5, and 8-10 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. On page 6, lines 15-19 of the March 20, 2007 Office Action, the Examiner acknowledges that the specification is enabling for an isolated nucleic acid molecule comprising or consisting of the nucleotide sequence of SEQ ID NO: 1 which encodes a polypeptide having the amino acid sequence of SEQ ID NO: 2, an expression vector comprising the same, and a host cell comprising the expression vector. However, the Examiner states that the specification allegedly is not enabling for an isolated nucleic acid molecule encoding a polypeptide comprising an amino acid sequence that is at least 90% identical to the amino acid sequence of SEQ ID NO: 2, or for an isolated nucleic acid molecule comprising a nucleotide sequence that is at least 80% identical to the nucleotide sequence of SEQ ID NO: 1. The rejection is respectfully traversed.

As discussed above, claims 1, 2, 3, and 5 have been amended. Also as discussed above, the amended claims are supported by the specification. In view of the amendments to claims 1, 2, 3 and 5 and the arguments below, the rejection of dependent claims 8-10 is believed to have been overcome.

The enablement requirement is met when the specification teaches a person of ordinary skill in the art how to make and use the claimed invention without "undue experimentation." *Enzo Biochem Inc. v. Calgene, Inc.*, 188 F.3d 1363, 1371-72 (Fed. Cir. 1999). The court in *Enzo Biochem* looked favorably on the factors set forth in *In re Wands* to consider in determining whether disclosure requires undue experimentation, which are: (1) the quantity of experimentation necessary, (2) the amount of direction of guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Enzo Biochem*, 52 USPQ 2d at 1135-1136 (quoting *In re Wands*, 8 USPQ 2d at 1404).

Applying the Wands factors to the facts set forth above to the claims as amended establishes that the current specification enables the claimed invention. At the time of filing of the application, the specification would have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. MPEP 2164.01(b) citing *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

In particular, the quantitative experimentation necessary to identify amino acid sequences that are at least 90% identical to the amino acid sequence of SEQ ID NO: 2 or nucleotide sequences that are at least 80% identical to the nucleotide sequence of SEQ ID NO:1 is not great, given the considerable advances in sequencing technology and genomic databases as of April 11, 2003, which is the filing date for both U.S. Provisional Application Serial Numbers 60/462,254 and 60/462,255 to which the current application claims priority. For example, on page 15, lines 10-12 and on page 4, lines 18-24 of the specification as filed, nucleic acid molecules are clearly contemplated that encode for amino acid polypeptides having a 90% sequence identity with the sequence of SEQ ID NO: 2 and for isolated nucleic acid molecules comprising a nucleotide sequences that are at least 80% identical to the nucleotide sequence of SEQ ID NO: 1.

Furthermore, it is not undue experimentation for a skilled worker to determine the breadth of the claimed sequences. The specification also teaches on page 11, lines 10-16, for example, how to determine sequence identity between any two nucleic acid molecules or two polypeptides using sequence comparison and alignment algorithms known in the art such as BLAST, FASTA, DNA Strider, and GCG package. In fact, these methodologies are fairly routine and standard experimental protocols for persons of skill in the art. Also, as discussed above, a person of skill in the art could readily envision all the DNAs degenerate to SEQ ID NO: 1 by using a genetic code table.

Additionally, a skilled worker with the current specification in hand would understand how to identify and isolate nucleic acid molecules polypeptides called for by the present claims. The instant specification provides clear guidance for identifying amino acid sequences that are at

least 90% identical to the amino acid sequence of SEQ ID NO: 2 or nucleotide sequences that are at least 80% identical to the nucleotide sequence of SEQ ID NO:1 (see, for example, page 11, lines 10-16 of the specification as filed). Example 1 on pages 36-38 of the application provides a methodology for identification, organization, and characterization of a putative *B. anthracis* luxS gene using the publicly available computer program BLASTN. Furthermore, Example 4 on pages 41-42 of the specification provides a methodology for identification of functional lux S protein. The sequences claimed are enabled by the specification. The specification teaches the skilled worker the structure of the sequences as well as how to identify nucleic acid sequences that encode for a *B. anthracis* luxS polypeptide.

When considering their breadth, the claims are fully enabled for the claimed scope in view of the details provided in the specification and Examples. Based on the foregoing remarks, Applicants submit that the present specification fully enables one of ordinary skill in the art to make and use the invention called for in the pending claims. Thus, it is believed that each one of the rejections under 35 U.S.C. § 112, second paragraph, has now been obviated. Withdrawal of these rejections is respectfully requested.

**Claim Rejection - 35 U.S.C. § 112, Second Paragraph ("Indefiniteness")**

Claims 2 and 8-10 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite because it is not clear if the polypeptide recited in claim 2 is different from the polypeptide recited in claim 1, and claims 8-10 depend directly or indirectly from claim 2.

To expedite prosecution of this application, claim 2 has been amended to clarify reference to the polypeptide recited in amended claim 1. In view of the amendment to claim 2, it is believed that the rejection to dependent claims 8-10 has been overcome. Thus, it is believed that amended claims 2 and 9 and original claims 8 and 10 obviate the rejection.

**Claim Rejection - 35 U.S.C. § 102(b)**

Claims 1-5 and 7 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Bourgogne *et al.*, *Abstracts of the 101st General Meeting of the American Society for Microbiology*, Orlando, FL, USA, page 127, May 20-24, 2001 (hereafter "Bourgogne"). The Examiner describes Bourgogne as teaching a putative *luxS* orthologue in *B. anthracis* that expresses a polypeptide having AI-2 activity and a recombinant *E.coli* host cell expressing the polypeptide. The Examiner also states that the disclosed *E.coli* host cell is expected to contain a vector.

Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. See M.P.E.P. §2131 (8th Ed. Rev. 4, 2006). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Every element of the claimed invention must literally present, arranged as in the claim. *Perkin Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed. Cir. 1984).

Amended claim 1 now recites SEQ ID NO: 2 and amended claim 5 now recites SEQ ID NO: 1. As discussed above, claim 7 has been amended to recite SEQ ID NO:1. Bourgogne does not teach the specific sequences called for in SEQ ID NOs: 1 or 2 as called for by the current claims. In fact, Bourgogne does not teach any of the sequences called for by the current claims.

Since Bourgogne fails to teach all of the elements of the claims, Bourgogne cannot anticipate the present application. Withdrawal of the rejection under 35 U.S.C. § 102(b) under Bourgogne is respectfully requested.

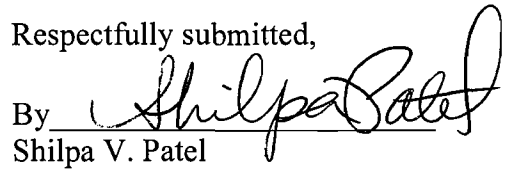
## CONCLUSION

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. Applicants reserve the right to pursue the canceled and/or non-elected subject matter in one or more continuation or divisional applications.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: September 19, 2007

Respectfully submitted,

By 

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